ATTACHMENT D

HEPATITIS B VACCINATION SERIES
INFORMATION SHEET AND CONSENT FORM

INFORMATION ON THE HEPATITIS B VACCINE

The Disease

Hepatitis means inflammation of the liver. Hepatitis B, which is a viral infection, is one of multiple causes of hepatitis. Most people with Hepatitis B recover completely, but approximately 5-50% become chronic carriers; 1-2% die of fulminant hepatitis. In the group of chronic carriers, many have no symptoms and appear well, yet can transmit the virus to others. Others may develop a variety of symptoms and liver problems varying from mild to severe (chronic persistent hepatitis, chronic active hepatitis, cirrhosis and liver failure). There is also an association between Hepatitis B virus and hepatoma (a form of liver cancer).

Hepatitis B virus can be transmitted by contact with body fluids including blood (including contaminated needles), semen, tears, saliva, urine, breast milk, and vaginal secretions. Health workers are at high risk of acquiring Hepatitis B because of frequent contact with blood or potentially contaminated body fluids and, therefore, vaccine is recommended to prevent the illness.

The Vaccine

"Engerix-B" (Hepatitis B Vaccine [Recombinant]) is a noninfectious Recombinant DNA Hepatitis B Vaccine. Clinical studies have shown that after three doses 96% of health adults have been seroprotected.

Persons with immune system abnormalities, such as dialysis patients, have less response to the vaccine, but over 67% of those receiving it do develop antibodies. If you have immune deficiency problems, you should obtain a written release from your physician.

Dosing Schedules

Three doses of Hepatitis B Vaccine are needed to confer protection. "Engerix-B" is administered at 0, 1, and 6 months or alternatively at a 0, 1, and 2 month regimen. This regimen is designated for protection of individuals at immediate risk of Hepatitis B infection -- those recently exposed to the virus (including needlestick exposure), certain travelers to high-risk areas, and neonates born of infected mothers. Studies have shown that 99% of subjects vaccinated with the 0, 1, 2 month dosing regimen have developed protective antibody titers by month 3.

Adverse Reactions

"Engerix-B" (Hepatitis B Vaccine {Recombinant}) is generally well tolerated. During clinical studies involving over 10,000 individuals distributed over all age groups, no serious adverse reactions attributable to vaccine administration were reported. As with any vaccine, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions not observed in clinical studies. The most frequently reported adverse reactions were injection-site soreness, fatigue, induration, erythema, swelling, fever, headache, and dizziness. Other more serious adverse reactions have occurred infrequently. If you have any questions about Hepatitis B or about "Engerix-B", please ask.

Contraindications

Hypersensitivity to yeast or any other component of the vaccine (e.g.: formalin or mercury derivatives) is a contraindication for use of the vaccine.

Warnings

Patients experiencing hypersensitivity after an "Engerix-B" (Hepatitis B Vaccine [Recombinant]) injection should not receive further injections of "Engerix-B" (see Contraindications).

Hepatitis B has a long incubation period. Hepatitis B Vaccination may not prevent Hepatitis B infection in individuals who have an unrecognized Hepatitis B infection at the time of vaccine administration. Additionally, small percentages of healthy people do not respond to the vaccine and do not develop immunity to the HBV.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with "Engerix-B." It is also not known whether "Engerix-B" can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. "Engerix-B" should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether "Engerix-B" is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when "Engerix-B" is administered to a nursing woman.

Approval from Physician

Approved for Vaccination: _____ Yes _____ No

_____ _____

Physician's Signature Date

CONSENT FORM

I, _____, have read the above statement about Hepatitis B and the Hepatitis B Vaccine, "Engerix-B". I have been provided with updated information and have had the opportunity to ask questions about the benefits and risks of Hepatitis B Vaccination. I understand that there is no guarantee that I will become immune and that there is a possibility that I will experience an adverse side effect from the vaccine.

For Women

I have been advised that studies have not been conducted to determine the effect of the vaccine on a developing fetus. Therefore, the safety of the vaccine is not known on the developing fetus. I have opted to receive the Hepatitis B vaccine, and hereby consent to the administration of three doses of the Hepatitis B Vaccine over the next 6 months.

_____ _____

Signature of the Recipient Date

_____ _____

Signature of the Witness Date